

REMARKS

Reconsideration and withdrawal of the rejections of the claims, in view of the remarks and amendments herein, is respectfully requested. Claims 1, 4-5 and 20 are amended, claims 3, 10-19, 27-28, and 33-38 are canceled, and claim 39 is added; as a result, claims 1-2, 4-9, 20-26, 29-30, 32, and 39 are now pending in this application. The amendments are intended to advance the application and are not intended to concede to the correctness of the Examiner's position or to prejudice the prosecution of the claims prior to amendment, which claims are in a continuation of the above-identified application.

Claims 10-19, 27-28, and 33-38 are canceled solely in response to the Restriction Requirement and without prejudice to their prosecution in an appropriately filed divisional application.

Support for claim 39 is found, for instance, in Table 1 and originally-filed claims 1-8.

The Examiner requested a courtesy copy of Forms 1449 and the documents filed with the Information Disclosure Statement filed on October 18, 2006. A copy of the Forms and each document is enclosed herewith.

With regard to support in U.S. application Serial No. 60/077,753 (the priority document for the present application) for the elected claims, the Examiner is respectfully requested to consider page 3, lines 3-5, page 13, lines 9-11, Figure 8 and Table 1 in the '753 application. Thus, the claims in the pending application are entitled to the benefit of the '753 application, filed on March 12, 1998.

The 35 U.S.C. § 101 Rejection

Claims 1-8 and 20 were rejected under 35 U.S.C. § 101. The amendments to claims 1 and 20, to recite "isolated" and "fusion polypeptide", respectively, address the § 101 rejection.

The 35 U.S.C. § 112 Rejections

Claims 1-8 and 20 were rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and enablement. These rejections are respectfully traversed.

In particular, with regard to written description, the Examiner asserts that the specification and claims do not indicate what distinguishing attributes are shared by the members of the genus, and that the specification and claims do not provide any guidance as to changes.

With regard to enablement, the Examiner asserts that it would require undue experimentation for one of skill in the art to make/use the cholesterol recognition/interaction amino acid consensus sequence having SEQ ID NO:26 and any peptide comprising a cholesterol interaction/recognition sequence encoded by SEQ ID NO:26.

The claims recite common structural attributes identifying the members of the genus, i.e., Z-(X)₀₋₅-Try-(X)₀₋₅-B, wherein Z is a neutral hydrophobic amino acid, B is a basic amino acid, and X is any amino acid. The specification discloses neutral hydrophobic amino acids and basic amino acids at page 10, lines 14-20. Numerous (19) exemplary cholesterol recognition/interaction amino acid sequences are disclosed in Table 1. Further, the specification discloses substitutions that altered cholesterol recognition of a particular cholesterol recognition/interaction amino acid sequence (see claim 29).

The claims also recite common functional attributes identifying the members of the genus, i.e., cholesterol recognition/interaction.

Therefore, the claims satisfy the written description requirement of § 112(1).

As acknowledged by the Examiner, the specification teaches a cholesterol recognition/interaction amino acid sequence in a peripheral-type benzodiazepine receptor (PBR) that is common to other proteins shown to interact with cholesterol (page 9 of the Office Action). Nevertheless, the Examiner points to Jamin et al. (Mol. Endocrin., 19:588 (2005)) and Li et al. (Endocrin., 139:4991 (1998)) to support the unpredictability of cholesterol recognition/interaction amino acid sequences having SEQ ID NO:26.

Even if, as the Examiner has suggested, the mechanism of binding and transporting of cholesterol by PBR is poorly understood (Jamin et al.), Applicant need not teach or suggest the mechanism by which a protein having a cholesterol recognition/interaction sequence binds cholesterol, to satisfy the enablement requirement of § 112(1). Similarly, even if the strength and specificity of the interaction of a protein having a cholesterol recognition/interaction sequence with cholesterol can vary (Li et al.), that is irrelevant to whether Applicant has taught

how to make and use the claimed peptides that include a cholesterol recognition/interaction amino acid consensus sequence.

If Applicant's invention is disclosed so that one of ordinary skill in the art can practice the claimed invention, even if the practice of the invention by the art worker includes routine screening or some experimentation, Applicant has complied with the requirements of 35 U.S.C. § 112, first paragraph. In re Angstadt, 190 U.S.P.Q. 214 (C.C.P.A. 1976); Ex parte Jackson, 217 U.S.P.Q. 804 (Bd. App. 1982).

Moreover, the Federal Circuit has explicitly recognized that the need, and methodologies required, to carry out extensive synthesis and screening programs to locate biomolecules with particular properties do not constitute undue experimentation. In re Wands, 8 U.S.P.Q.2d 1400, 1406-1407 (Fed. Cir. 1988), the Court stated:

The nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibody with desired characteristics. Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody.

Likewise, practitioners in the art related to the present application would be well-equipped to prepare and screen peptides with amino acid sequences within the scope of claim 1 to identify those with cholesterol recognition/interaction amino acid sequences. See also, Hybritech Inc. v. Monoclonal Antibodies Inc., 231 U.S.P.Q. 81, 84 (Fed. Cir. 1986) (evidence that screening methods used to identify characteristics [of monoclonal antibodies] were available to art convincing of enablement). Evidence that it is within the skill of the art to prepare and screen peptide libraries is provided in the abstract for Cheng et al., Proc. Natl. Acad. Sci. USA, 94:14120 (1997); Apletalina et al., J. Biol. Chem., 273:26589 (1998); and He et al., J. Gen. Virol., 79:3145 (1998) (a copy of each is included herewith).

Therefore, the specification enables the claimed invention.

Thus, withdrawal of the § 112(1) enablement rejection is respectfully requested.

The 35 U.S.C. § 102 Rejection

Claims 1-8 and 20 were rejected under 35 U.S.C. § 102(b) as being anticipated by Garnier et al. (Molecular Pharmacology, 45:201 (1994)). This rejection, as it may be maintained with respect to the pending claims, is respectfully traversed.

Garnier et al. disclose the cloning and expression of a murine PBR cDNA and the encoded amino acid sequence of murine PBR. Applicant is unable to find in Garnier et al. any teaching or suggestion of the region in PBR that is a cholesterol recognition/interaction sequence.

Accordingly, withdrawal of the § 102(b) rejection is respectfully requested.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date

October 1, 2007

By

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In re Application of: Vassilios Papadopoulos, *et al*
Application No.: 09/623,922
Filing Date: August 31, 2001
Title: CHOLESTEROL RECOGNITION SEQUENCE

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October 1, 2007
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